UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ADAM PAXTON, Individually and On Behalf of All Others Similarly Situated, Plaintiffs, v. PROVENTION BIO, INC., ASHLEIGH PALMER, and ANDREW DRECHSLER, Defendants.	Civil Action No. 3:21-cv-11613

OPINION

Plaintiffs George L. Jordan, Jr. and Adam Paxton, individually and on behalf of all others similarly situated, filed an amended class action complaint ("CAC") against Provention Bio, Inc. (the "Company"), its founder and Chief Executive Officer Ashleigh Palmer, and its Chief Financial Officer Andrew Drechsler (collectively, "Defendants"), alleging securities fraud in connection with statements and omissions concerning teplizumab, the Company's candidate drug for delaying Type One Diabetes ("T1D"). ECF No. 32 (CAC) ¶¶ 1-2, 25, 26. Before the Court is Defendants' motion to dismiss the CAC pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b). ECF No. 44. For the reasons below, Defendants' motion will be granted.

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Teplizumab is a drug intended to delay or prevent the progression of T1D. CAC ¶ 58. T1D is an autoimmune disease that generally progresses in three stages—Stage 1,

[1] Plaintiffs object to the Court considering "nearly two-thirds" of the Exhibits Defendants submitted in connection with their motion to dismiss. Pl. Br. at 22 (citing Exs. 1-11, 13-17, 29-30, 32-37). Many of those documents (Exs. 1-3, 5-6, 9, 11, 13-15, 30, 32-34), however, are ones Defendants were required to file with the SEC, see, e.g., Form 8-K, S.E.C., https://www.sec.gov/fast-answers/answersform8k, and to which the public has "unqualified access," Pension Ben. Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1197 (3d Cir. 1993). Accordingly, the SEC-filed documents are "matters of public record of which the court can take judicial notice," and the Court does so here. Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014); see also In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1331 (3d Cir. 2002) (affirming a District Court's noticing "documents filed with the SEC, but not relied upon in the Complaint").

In addition, one of the exhibits was created by the FDA and the other was produced by the FDA during the review process, and both are publicly available on the FDA's website. See Exs. 29, 37. Courts regularly take notice of such documents. See, e.g., Kos Pharms., Inc. v. Andrx Corp., 369 F.3d 700, 705 n.5 (3d Cir. 2004); In re Egalet Corp. Sec. Litig., 340 F. Supp. 3d 479, 496-97 (E.D. Pa. 2018), aff'd sub nom. Spizzirri v. Zyla Life Scis., 802 F. App'x 738 (3d Cir. 2020); see also, e.g., Sierra Club v. United States Env't Prot. Agency, 964 F.3d 882, 893 n.9 (10th Cir. 2020); United States v. Garcia, 855 F.3d 615, 621-22 (4th Cir. 2017); Wildman v. Medtronic, Inc., 874 F.3d 862, 866 n.2 (5th Cir. 2017); Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011); United States ex rel. Dan Abrams Co. v. Medtronic, Inc., No. 15-CV-01212, 2018 WL 5266863, at *2 n.3 (C.D. Cal. June 7, 2018); In re Zyprexa Prod. Liab. Litig., 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008). The Court therefore takes notice of these documents as well.

As for the objected-to non-SEC-filed press releases and earnings call transcript (Exs. 4, 7-8, 10, 16-17, 35), the Court concludes, contrary to Plaintiffs' contention, Pl. Br. at 21-22, that they are integral to the CAC, see Schmidt, 770 F.3d at 249; see also CAC Intro. (stating the allegations are "based upon . . . a review of Defendants' public documents, conference calls, and announcements . . ."). They are also from the same sources and of the same type as other documents to which Plaintiff do not object, and Plaintiffs also do not question their authenticity. Although the Court may consider them, see Pension Ben. Guar. Corp., 998 F.2d at 1196-97, it will not because they are

Stage 2, and Stage 3—corresponding to decreasing cell function. CAC ¶¶ 50-52. After the University of Chicago developed teplizumab, MacroGenics, Inc. acquired it in 2005 and partnered with Eli Lilly to manufacture the drug in Ireland and conduct clinical trials testing whether teplizumab could delay the progression of T1D in newly diagnosed Stage 3 T1D patients (the "Stage 3 clinical trial"). CAC ¶ 56. In 2010, the Stage 3 clinical trial concluded that teplizumab failed to delay the progression of T1D in Stage 3 T1D patients, and MacroGenics halted development of the drug. CAC ¶ 56.

The following year, the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDKD") and TrialNet spearheaded another clinical trial to test whether teplizumab could delay the progression of T1D in at-risk Stage 2 T1D patients and prevent progression to Stage 3 T1D (the "Stage 2 clinical trial"). CAC ¶¶ 57-60. In June 2019, the Stage 2 clinical trial announced positive results, concluding that "a single 14-day course of teplizumab in patients with Stage 2 T1D significantly delayed the median onset of clinical Stage 3 T1D by a minimum of two years compared to the placebo" and "more patients who took teplizumab remained free of clinical Stage 3 T1D beyond five years compared to patients who took the placebo." CAC ¶¶ 60-61. TrialNet published the results of the Stage 2 clinical trial, which ultimately involved seventy-six participants

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unnecessary to the resolution of the motion. The Court does not take notice of the presentation Defendants filed, Ex. 36, as they have provided no information regarding the document's origins, and it does not appear to be integral to the CAC.

The Court also takes notice of the documents on which "Plaintiffs take no position." Pl. Br. at 21 (citing Exs. 12, 18-28, and 31). First, many of the documents (Exs. 19, 21-22, 24-26, 28) are "public records" or publicly available FDA-created documents of which the Court may take notice. Second, these documents are "integral to or explicitly relied upon in the complaint." Schmidt, 770 F.3d at 249.

(forty-four of whom were treated with teplizumab and thirty-two of whom were given a placebo), in the New England Journal of Medicine on August 15, 2019. See CAC ¶ 84; Kevan C. Herold, et al., An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes, 381 New Eng. J. Med. 603-13 (August 15, 2019), https://www.nejm.org/doi/pdf/10.1056/NEJMoa1902226?articleTools=true.[2]

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In May 2018, while the Stage 2 clinical trial was ongoing, the Company acquired teplizumab from MacroGenics. CAC ¶¶ 2-3, 49. A few months later, the Company contracted with AGC Biologics to manufacture the drug in Seattle, Washington. CAC ¶ 49. After release of the positive results of the Stage 2 clinic trial, the Company applied for a Breakthrough Therapy Designation for teplizumab, which the U.S. Food and Drug Administration ("FDA") granted in August 2019. CAC ¶¶ 4, 64. A Breakthrough Therapy Designation expedites the FDA's review of a drug "and is only given to potential drugs that are intended to treat a serious condition and [where] preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint[]." CAC ¶ 64. The designation also allows a developer to submit a Biologics License Application ("BLA") on a rolling basis

[2] The Court takes judicial notice of this publicly available scientific publication that is referenced in, and relevant to, the CAC, see CAC ¶ 84, but only for "the publication of such information," not for "the truth of the matter asserted" therein, see Abdin v. CBS Broad. Inc., 971 F.3d 57, 60 n.2 (2d Cir. 2020) ("The district court properly took judicial notice of the [scientific] publications discussed herein . . . not necessarily for the truth of the matter asserted, but for the publication of such information[.]").

and obtain priority review. CAC ¶ 4. If granted, a BLA permits the developer to introduce the drug into interstate commerce. CAC ¶ 33. Generally, a BLA requires the developer to show that its drug is safe to use and safely manufactured. CAC ¶ 36 (citing 42 U.S.C. § 262(a)(2)(C)).

On April 16, 2020, the Company announced the start of its rolling submission of a BLA for teplizumab. CAC ¶ 65. Because the Company's BLA relied on the Phase 2 clinical trial that used teplizumab manufactured in Ireland, and the Company would be manufacturing its teplizumab in Seattle, the Company had to demonstrate that the two drugs were "biocomparable." CAC ¶¶ 37, 66. To accomplish this, the Company conducted a bridging study to show that the Ireland-manufactured drug and its Seattle-manufactured drug "ha[d] a similar lasting impact on a patient's body in both time and effect" (the "Bridging Study"). CAC ¶¶ 67-69. The Bridging Study analyzed pharmacokinetic ("PK") and pharmacodynamic ("PD") data. CAC ¶ 67. PK refers to the "activity of drugs in the body over a period of time, including the process by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted" (i.e., time data), CAC ¶ 67, and PD refers to "how the body reacts to a drug" (i.e., effect data), CAC ¶ 67. The "traditional" measure of PK is called "area-under-the-curve" ("AUC"). CAC ¶¶ 37, 68. In this context, AUC refers to the area underneath a curved line on a graph of data where the y axis is concentration of the drug in the body and the x axis is time—meaning AUC "reflects the actual body exposure to a drug after the administration of a dose" with a higher AUC corresponding to increased concentration of the drug in the body at that particular point in time along the x axis. CAC ¶¶ 37, 68. The Bridging

Study was the first time the Company's Seattle-manufactured teplizumab was tested on humans. CAC ¶ 72.

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In November 2020, the Company completed its rolling BLA submission. CAC ¶ 6. The Company issued a press release on November 2, 2020 stating that its submission "represent[ed] a . . . critical step toward the potential first major advancement in T1D therapudics since insulin was introduced a century ago," and the Company "look[ed] forward to continuing on [its] path toward changing the current treatment paradigm for T1D and, if approved, bringing teplizumab, designated by the FDA as a Breakthrough Therapy, to the U.S. market in 2021." CAC ¶ 75 (emphasis omitted); Ex. 18 at 1-2. The Company's stock price rose about 18% in the following two days. CAC ¶ 77.

On November 5, 2020, the Company issued another press release, held an earnings call, and filed a Form 10-Q. The press release stated that the Company was "excited about the progress [its] team has made in recent months as [it] work[ed] to redefine the treatment landscape for T1D," reiterated that the Company's "completion of the rolling BLA submission for teplizumab" was a "major milestone," and stated that the Company was "focused on preparing for a potential product approval and launch in mid-2021." CAC ¶ 78 (emphasis omitted).

On the earnings call, Palmer noted the Company's "positive manufacturing progress," recapped the positive results of the Stage 2 clinical trial, and explained that "[t]hroughout the remainder of 2020, [the Company] plan[s] to transition and transform

. . . into a commercialization ready organization in anticipation of the potential launch of teplizumab next year." CAC ¶¶ 80-81 (emphasis omitted).

The Form 10-Q added that "[i]n June 2020, extended follow-up data from the [Stage 2 clinical trial] was announced which showed that a single 14-day course of teplizumab significantly delayed the onset of T1D in [a]t-[r]isk patients by a median of approximately three years compared to the placebo," and "no additional safety signals ha[d] been noted [and] the results showed that teplizumab's effect on delaying the onset of clinical T1D was not only consistent from previous analyses, but was durable and now extended to a median of at least three years." CAC ¶¶ 84-85 (emphasis omitted). The Form 10-Q also noted that the Company may not be able to "successfully start and complete clinical trials and obtain regulatory approval for the marketing of [the Company's] product candidates." CAC ¶ 83 (emphasis omitted); Ex. 19 at 3 (emphasis omitted).

On November 18, 2020, Palmer spoke at a virtual healthcare conference and stated, "Not only are the results of the [Stage 2 clinical trial] highly statistically significant . . . , they are also highly clinically relevant," and that the Company "successfully completed the transfer of teplizumab's prior commercial scale manufacturing process from Eli Lilly's manufacturing facility in Ireland to [the Company]'s contract manufacturing partner AGC Biologics in Seattle." CAC ¶ 88-89 (emphasis omitted).

On December 10, 2020, an analyst reported that a Company representative stated that the Company "expect[ed] an [FDA] advisory committee [to review its application] . . . and [the Company] would be ready for one if need be." CAC ¶ 91 (citations omitted).

On January 4, 2021, the Company issued another press release announcing that the FDA officially filed the teplizumab BLA, granted the Company's request for priority review, and scheduled an advisory committee meeting for May 2021. CAC ¶ 92; Ex. 20 at 1. The press release also stated that the Company "intend[s] to work closely with the FDA to support their review while also preparing for a potential product launch in the third quarter of 2021." CAC ¶ 92 (emphasis omitted); Ex. 20 at 1. The Company's stock price rose 7.79% from December 31, 2020 to January 4, 2021. CAC ¶ 95.

At a conference with biotech investors on January 11, 2021, Palmer stated that "we should have an approval decision on or around July 2 of this year[,] [a]nd especially given the extremely convincing nature of the [Stage 2 clinical trial] data, I think we can all agree that the advisory committee meeting should go well." CAC ¶ 97 (emphasis omitted).

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On January 12, 2021, the Company conducted a stock offering of six million shares of common stock. CAC ¶ 98. The offering materials listed the Bridging Study as a "risk factor." CAC ¶ 98; Ex. 21 at 3. Specifically, the stock offering stated that "[t]he results of our. . . [B]ridging [S]tudy . . . may be unacceptable to the regulatory authorities." Ex. 21 at 3. The offering materials also stated the following:

> We believe, based on the data and our analysis, that the results of the [] [B]ridging [S]tudy suggest that the drug substances manufactured by AGC Biologics and Eli Lilly are comparable. Comparison of drug plasma concentration versus time after dosing shows a lower area under the curve, or AUC, for the [teplizumab] derived from the drug substance manufactured by AGC Biologics. Based on our PK/PD modeling, we do not believe this lower AUC is significant enough to impact the efficacy or safety of the to-be-commercialized [teplizumab] when used as proposed in our BLA filing. . . . The FDA could disagree with our analysis and interpretation of the [] [B]ridging [S]tudy, including with respect to the observed lower AUC, and, as a result, could require additional analyses and modeling, or additional information from ongoing or new studies to support the commercial use of the [teplizumab] derived from the drug substance manufactured by AGC Biologics.

CAC ¶ 98 (emphasis omitted); Ex. 21 at 3. The Company's stock price dropped 14.34% from January 12 to 13, 2021. CAC ¶ 100.

On February 25, 2021, the Company filed its Form 10-K, issued a press release, held an earnings call, and participated in a healthcare conference. The Form 10-K detailed the Company's view of the Bridging Study results, as well as the FDA's view. CAC ¶ 101. As for the Company's view, the Form 10-K stated,

> We believe, based on the data and our analysis, that the results of the [Bridging] [S]tudy suggest that the drug substances manufactured by AGC Biologics and Eli Lilly are comparable. Comparison of drug plasma concentration versus time after dosing shows a lower AUC, for the teplizumab drug product derived from the drug substance manufactured by AGC Biologics. Based on our PK/PD modeling, we do not believe this lower AUC is significant enough to clinically impact the efficacy or safety of the to-be commercialized teplizumab drug product when used as proposed in our BLA filing.

CAC ¶ 101 (emphasis omitted); Ex. 22 at 4. As for the FDA's view, the Form 10-K continued,

> At our February 2021 mid-cycle review meeting with FDA, among other matters, we addressed various questions and preliminary concerns raised by

> FDA relating to the [Bridging] [S]tudy results and our conclusions, including that we believe study results support PD comparability and that our modeling supports that the lower PK AUC, which potentially indicates that the drug substance manufactured by AGC Biologics may have cleared faster from the blood stream than the drug substance manufactured by Eli Lilly, should not impact safety or efficacy in a clinically meaningful way. At the meeting, FDA indicated that they will be providing us with various additional information requests which we plan to address promptly after receipt. The FDA stated it could not comment on a resolution to its concerns relating to the [Bridging] [S]tudy results at the meeting.

CAC ¶ 101 (emphasis omitted); Ex. 22 at 4. The Form 10-K then warned,

> Ultimately, there is no guarantee that the FDA will agree with our analysis and interpretation of the [] [B]ridging [S]tudy, including with respect to the observed lower AUC and, as a result, the agency could require additional analyses and modeling, or additional information from ongoing or new studies to support the commercial use of the teplizumab drug product derived from the drug substance manufactured by AGC Biologics. If we are unable to satisfy the FDA's comparability requirements, the timing of the FDA's review and decision on the teplizumab BLA could be delayed, or its approvability negatively impacted, including the potential issuance of a complete response letter, which would have a material adverse impact on our business.

CAC ¶ 101 (emphasis omitted); Ex. 22 at 4.

The press release reiterated that "[t]he FDA's filing of our BLA for teplizumab represents a momentous achievement" and that the Company "look[ed] forward to working closely with the FDA to support the Agency's Priority Review, while [] prepar[ing] for a potential commercial launch in the second half of this year." CAC ¶ 109 (emphasis omitted).

On the earnings call, Palmer stated that "[t]he momentum we accelerated throughout 2020 continues to be driven forward into 2021," reiterated the Company's and FDA's view of the Bridging Study results, stated that "all of the parameters were within

the anticipated target, especially the PD parameters which are more indicative of the efficacy in the safety with the exception of this AUC PK area under the curve" and that "the AGC Biologics' [metrics] were slightly below the target, indicating that it cleared [the blood stream] a little faster," and emphasized that the Company "do[es] not believe that the difference in area under the curve will result in a clinically relevant difference in the safety and the efficacy of teplizumab" and "we have confiden[ce] in the interpretation that we have submitted to [the FDA]." CAC ¶ 111-12 (emphasis omitted); Ex. 23 at 4-11.

At the healthcare conference, Palmer explained the challenges with replicating the Ireland-manufactured drug, stating,

> [T]he Lilly drug substance from which the original material was derived used in the [Stage 2 clinical trial] was produced a decade ago [and] wasn't validated and is no longer available. We have material that we've been able to compare the drug product [to] resulting from that process with the material that we have produced at AGC Biologics as a result of a technology transfer. And from a manufacturing point of view, the material is comparable.

CAC ¶ 114 (emphasis omitted). Palmer explained that the Bridging Study used "a single dose in healthy volunteers," and "there was one Pharmacokinetic component, which we refer to as the area under the curve, which you can essentially assume means [] the rate at which the material clears from the bloodstream, and that component in that particular study missed the target." CAC ¶ 114 (emphasis omitted). Palmer added that "we believe that the material is comparable and we believe that there are no clinically relevant consequences from that AUC difference[,] nothing with respect to safety[,] and nothing with respect to efficacy and we presented that to the agency," but the FDA told the

Company that "they want to do their own modeling . . . to validate [the Company's] modeling and [] assumptions." CAC ¶ 114 (emphasis omitted). The Company's stock dropped 12.42% from February 24 to 25, 2021. CAC ¶ 117.

On March 3, 2021, the Company issued a press release to announce the extended follow-up data from the Stage 2 clinical trial. CAC ¶ 118. Those results showed that "that a single 14-day infusion course of teplizumab [] delayed the onset of clinical disease and insulin dependence in at-risk type 1 diabetes (T1D) patients by approximately three years (median of 32.5 months), adding one year to previously reported results." CAC ¶ 118. The press release added that "[o]utcomes such as these validate [the Company's] mission to intercept and prevent debilitating and life-threatening diseases" and that the FDA's response to the BLA was expected to be on July 2, 2021. CAC ¶ 118 (emphasis omitted).

At a virtual life sciences conference on March 9, 2021, Drechsler elaborated on more positive results from the extended follow-up data from the Stage 2 clinical trial, noting that "one subject has yet to develop clinical type 1 diabetes more than eight years after their initial receipt of teplizumab" and "[t]hese are remarkable results." CAC ¶ 120 (emphasis omitted). Drechsler added that "[t]here are over 800 patients that have been treated with teplizumab through its development lifecycle, and this represents a solid safety database for us." CAC ¶ 120 (emphasis omitted).

At a healthcare conference on March 16, 2021, Palmer fielded additional questions about the Bridging Study and its results. CAC ¶ 122. Palmer repeated that the Bridging Study involved a "single dose [of the drug] . . . in healthy volunteers," and "there was one

PK parameter, the area under the curve, [that] . . . suggested [the] AGC product might clear [the blood stream] a little faster." CAC ¶ 122 (emphasis omitted). Palmer added that the Company conducted "extensive modelling" to show that "any differences w[ould] not be clinically relevant when you scale up [the] doses [to] . . . 14 consecutive days." CAC ¶ 122 (emphasis omitted). Palmer also touted the Company's relationship with the FDA, stating that "we have a wonderful relationship with the agency," which has "been incredibly supportive throughout the rolling submission and we have a good open dialog with them and we anticipate a continuing discussion around this." CAC ¶ 124 (emphasis omitted). Palmer added that "certainly [the FDA's] feedback is likely to come before a decision [along with] more questions or discussion around the modeling," but the Company does not "anticipate that this would be an [advisory committee] issue because it really doesn't require input from patients or from clinical experts," but instead is "really a technical assessment and we are hopeful that when the agency has had a chance to do its modeling and address all of its information requests that they have come to the same conclusion that we have." CAC ¶ 124 (emphasis omitted).

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On April 8, 2021, the Company issued a press release detailing the FDA's April 2, 2021 feedback on the Bridging Study. CAC ¶ 127. Specifically, the press release explained that the FDA "identified deficiencies that preclude[d] discussion of labeling and post-marketing requirements/commitments at this time." CAC ¶ 127; Ex. 24 at 2. The Company continued that the FDA "indicated that based on the data it ha[d] reviewed to date, the Agency's position [wa]s that the PK profiles of the two drug products

evaluated in the PK/PD [B]ridging [S]tudy were not comparable and that additional data would be required before the FDA's considerations could be satisfied." CAC ¶ 127 (emphasis omitted); Ex. 24 at 2. The Company's stock price fell 17.78% from April 8 to April 9, 2021. CAC ¶ 128.

On April 27, 2021, the Company issued a press release detailing discussions it had with the FDA on April 23, 2021. CAC ¶ 130; Ex. 25 at 3. The press release explained that the FDA "concluded that the PK profiles of the Eli Lilly-teplizumab and the AGC-teplizumab evaluated in the Bridging Study" were "not comparable, since the intended commercial product did not meet the pre-specified 80-125% PK area under the curve (AUC) comparability target range," and the FDA could not "be certain if this observation is not clinically relevant." CAC ¶ 130 (emphasis omitted); Ex. 25 at 3. The press release continued that "the FDA's PK comparability considerations are likely to result in a delay in potential BLA approval timelines and that the specifics of such delay will depend upon the outcome of ongoing discussions with the FDA to find a solution." CAC ¶ 130 (emphasis omitted); Ex. 25 at 3. The press release added that the FDA suggested "the removal of the term 'prevention' from the previously proposed indication, as the remaining term 'delay' more accurately reflect[ed] the results of the [Stage 2 clinical trial]." CAC ¶ 131; Ex. 25 at 3.

On May 6, 2021, the Company filed a Form 10-Q and held an earnings call where it continued to discuss the results of its Bridging Study. CAC ¶ 133. The Form 10-K stated that the Company's "rolling BLA submission for teplizumab in the [a]t-risk

indication has been initiated and is currently on track to be finalized upon completion of the CMC[3] module by the end of 2020," but

> [t]he potential approval of the teplizumab BLA is subject to satisfactorily addressing issues raised by the FDA including its conclusion that the drug pharmacokinetic profiles of the two drug products evaluated in our [] [B]ridging [S]tudy for teplizumab are not comparable[,] [which] may require further development activities and additional data and will likely affect the timing of the review of and decision by the FDA on our BLA submission.

CAC ¶¶ 137-38 (emphasis omitted); Ex. 26 at 4, 8.

On the call, Palmer explained that the Company "conducted a single low dose [] [B]ridging [S]tudy in healthy volunteers and [] observed a PK area under the curve or AUC level below the target comparability range," which meant that "the new drug product might be clearing from the bloodstream faster than drug product manufactured from the old Lilly drug substance." CAC ¶ 133 (emphasis omitted); Ex. 26 at 5. Palmer highlighted that "[i]mportantly, . . . we believe that other relevant PK/PD parameters . . . all fell within acceptable ranges of comparability," CAC ¶ 133 (emphasis omitted); Ex. 27 at 5, but explained that the FDA "informed [the Company] that it d[id] not yet consider the two drug products to be sufficiently comparable and cannot be certain [whether] the PKAUC short-haul observed in our single low-dose [] [B]ridging [S]tudy in healthy volunteers [] translate[s] into clinical relevance." CAC ¶ 133 (emphasis omitted); Ex. 27 at 5. Palmer explained that the results of the Bridging Study "became available at the beginning of the year." CAC ¶ 135 (emphasis omitted); Ex. 27 at 10-11. Palmer added that "the FDA continues to be very engaged, very helpful and very cooperative and

[3] "CMC" refers to "chemistry, manufacturing[,] and controls." CAC ¶ 74.

has agreed to work closely with us to figure out our next steps and the path forward to a solution, which we anticipate will likely require our provision of additional data to support PK/PD comparability," CAC ¶ 133 (emphasis omitted); Ex. 27 at 5, but noted that "there is likely to be a delay based on our understanding of the agency's position on comparability, [and] we've not had discussions on how that delay will manifest itself whether it will be within the current review cycle with some extension or after a formal response," CAC ¶ 136 (emphasis omitted); Ex. 27 at 14-15. On the call, the Company's Chief Scientific Officer Francisco Leon also said, "[a]s to why [the Bridging Study results] were below [the AUC] target, the honest answer is, we still don't know." CAC ¶ 134 (emphasis omitted); Ex. 27 at 9. The Company's stock dropped 6.02% from May 7 to May 10, 2021. CAC ¶ 139.

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On May 25, 2021, the FDA released briefing documents for the upcoming Advisory Committee meeting. CAC ¶ 142. The briefing "disclosed that the mean AUC" for the Seattle-manufactured teplizumab "was less than half . . . of the AUC" of the Ireland-manufactured teplizumab. CAC ¶ 142 (emphasis omitted). The briefing noted that the reason for the AUC disparity appeared to be a faster clearance of the Seattle-manufactured teplizumab from the circulation and not any differences in the strengths of the two drugs. CAC ¶ 142.

The Advisory Committee held a meeting on May 27, 2021, and the Company presented teplizumab for review. CAC ¶ 144. The Advisory Committee expressed concerns about (1) "the size and scope of the [Stage 2 clinical trial], including the fact

that [it] did not meet its enrollment goal and only ended up testing the [drug] on 44 patients as opposed to the 71 patients called for by the trial protocol," and (2) "the fact that the [Stage 2 clinical trial] did not follow patients after their diabetes diagnosis, leaving a gap in knowledge about long term safety of the [Company's] teplizumab." CAC ¶ 144 (emphasis omitted). Ultimately, the Advisory Committee voted 10-7 in favor of recommending FDA approval of teplizumab for delay of T1D. CAC ¶ 145. The Company's stock price fell 28.74% from May 27 to May 28, 2021. CAC ¶ 146.

At a healthcare conference on June 3, 2021, Palmer explained the 10-7 vote as "yet another significant step closer to teplizumab potential commercialization, although it is only one consideration FDA will be taking into account when reviewing our Teplizumab BLA." CAC ¶ 147. The Company's stock price fell 3.60% from June 2 to June 3, 2021. CAC ¶ 148.

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On July 6, 2021, the Company announced the results of the FDA's Complete Response Letter ("CRL"), which the Company received on July 2, 2021. CAC ¶ 149; Ex. 31 at 2. The Company explained that the CRL concluded that the Bridging Study failed to show PK comparability and the Company would "need to establish PK comparability appropriately between the intended commercial product and the clinical trial product or provide other data that adequately justify why PK comparability is not necessary," since "PK remains the primary endpoint for demonstration of comparability between the two products." CAC ¶ 149 (emphasis omitted); Ex. 31 at 3. The Company responded to the FDA's concern about the Bridging Study's PK results by explaining that the Company

"expects relevant additional PK/PD data . . . to be[] collected from a PK/PD substudy in patients receiving 12-days of therapy in [an] ongoing Phase 3 [clinical] trial in newly diagnosed T1D patients later this quarter" and the "data will be analyzed by independent, unblinded third-parties to maintain the integrity of this placebo-controlled trial." CAC ¶ 149; Ex. 31 at 3. The Company added that the FDA observed "certain deficiencies" in the Company's manufacturing facility would need to be resolved before FDA approval, CAC ¶ 150 (emphasis omitted), but noted that the deficiencies "conveyed during a recent general inspection [were] not specific to telizumab," Ex. 31 at 3. The Company's stock price fell 26.38% after this announcement. CAC ¶ 151.

B

On May 21, 2021, Paxton filed a class action complaint against Defendants alleging securities fraud in violation of § 10(b) of the Exchange Act, 15 U.S.C. §78j(b), Rule 10b-5 promulgated thereunder, 17 C.F.R. 240.10b-5, and § 20(b) of the Exchange Act, 15 U.S.C. § 78t(a). ECF No. 1. After the District Court appointed lead counsel and Jordan as lead Plaintiff, see ECF No. 28, Plaintiffs filed an amended class action complaint (CAC) that added factual allegations, see ECF No. 32 (CAC). Generally, Plaintiffs allege that Defendants' made material misrepresentations in various of their public filings, press releases, earnings calls, and statements at conferences from November 2, 2020 through July 6, 2021 (the "Class Period"), CAC ¶ 1, by repeatedly omitting the following:

> (i) [the Company]'s Bridging Study had not shown[4] PK comparability, thereby seriously compromising [the Company]'s ability to utilize the [Stage 2] clinical trial as evidence supporting approval of its version of the teplizumab BLA;
> (ii) [the Stage 2 clinical trial] did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol;
> (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got [T1D] after being treated;
> (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns;
> (v) [the Company]'s manufacturing facilities for teplizumab were deficient;
> (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for [sic] secure FDA approval;
> (vii) the teplizumab BLA lacked the evidentiary support [for the approval of teplizumab to delay T1D and] the Company had led investors to believe it possessed [such evidentiary support]; and
> (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

See e.g., CAC ¶ 140.

Defendants moved to dismiss the CAC. ECF No. 44. Plaintiffs opposed the motion, ECF No. 53, and Defendants replied, ECF No. 55. The matter was assigned to the undersigned for the limited purpose of addressing the motion to dismiss. ECF No. 56.

II[5]

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[4] Plaintiffs also allege that prior to January 12, 2021, the Company failed to disclose that "there was significant risk that [the Company's] Bridging Study had not shown PK comparability[.]" CAC ¶¶ 76, 79, 82, 83, 86, 90, 93.

[5] On a Rule 12(b)(6) motion, the Court "accept[s] all factual allegations in the complaint as true and construe those facts in the light most favorable to the plaintiff[]." Newark Cab Ass'n v. City of Newark, 901 F.3d 146, 151 (3d Cir. 2018). The complaint must "contain sufficient factual allegations, taken as true, to state a claim to relief that is plausible on its face." Id. (citation and quotation marks omitted). Because this is a securities fraud class action, we must also apply the heightened pleading

Section 10(b) of the Securities Exchange Act prohibits the "use or employ[ment], in connection with the purchase or sale of any security . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Securities and Exchange Commission ("SEC") Rule 10b-5, which implements § 10(b), provides that it is unlawful "[t]o make any untrue statement of a material fact or to omit . . . a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). To a state a claim under § 10(b) and Rule 10b-5, a plaintiff must allege: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentations or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 37-38 (2011) (quotation marks and citation omitted).

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requirements for allegedly misleading statements or omissions as set forth in the PSLRA, meaning "[t]he complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1); Williams v. Globus Med., Inc., 869 F.3d 235, 240 (3d Cir. 2017). All securities fraud claims are also subject to Rule 9(b), which similarly requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); Williams, 869 F.3d at 240. "Accordingly, [f]ailure to meet the threshold pleading requirements demanded by Rule 9(b) and the PSLRA justifies dismissal apart from Rule 12(b)(6)." Williams, 869 F.3d 241 (internal quotation marks and alterations omitted).

Defendants argue that Plaintiffs have failed to allege three elements: material misrepresentations or omissions, scienter, and loss causation. See Def. Br. at 27-65. Each element will be addressed in turn.

A

Plaintiffs allege that several of Defendants' statements during the Class Period were misleading because they omitted information concerning (1) the comparability results of the Bridging Study,[6] (2) the enrollment size of the Stage 2 clinical trial,[7] (3) ongoing safety data from the Stage 2 clinical trial,[8] and (4) manufacturing progress.[9] See CAC ¶¶ 8-9, 76, 79, 82, 86, 90, 93, 99, 104, 108, 113, 115, 119, 123, 125, 140. Each category will be addressed in turn.

1

[6] See, e.g., CAC ¶¶ 76(i) ("[T]here was significant risk that [the Company]'s Bridging Study had not shown PK comparability, thereby seriously compromising [the Company]'s ability to utilize the [Stage 2] clinical trial as evidence supporting approval of its version of the teplizumab BLA[.]"), 99(i) ("[The Company]'s Bridging Study had not shown PK comparability, thereby seriously compromising [the Company]'s ability to utilize the [Stage 2] clinical trial as evidence supporting approval of its version of the teplizumab BLA[.]").

[7] See, e.g., CAC ¶ 76(ii) ("[The Company]'s pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol[.]").

[8] See, e.g., CAC ¶¶ 76(iii) ("[T]he safety data for teplizumab was insufficient because it was unclear what happened to study participants who got T[1D] after being treated[.]"), 76(iv) ("[T]eplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns[.]").

[9] See, e.g., CAC ¶ 76(v) ("[The Company]'s manufacturing facilities for teplizumab were deficient[.]").

The Company did not make any material omissions concerning the comparability results of the Bridging Study throughout the Class Period.

a

First, omission of the risk of the Bridging Study producing negative results in statements from the beginning of the Class Period until January 12, 2021 does not render these statements actionable.

While material omissions can be actionable, "Section 10(b) and Rule 10b-5 do not create an affirmative duty to disclose any and all material information." City of Edinburgh v. Pfizer, Inc., 754 F.3d 159, 174 (3d Cir. 2014) (quotation marks omitted). "Disclosure is required . . . only when necessary to make . . . statements made, in the light of the circumstances under which they were made, not misleading." Id. (quotation marks omitted). This means that "[o]nce a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading." Williams v. Globus Med., Inc., 869 F.3d 235, 241 (3d Cir. 2017).[10] In other words, "[c]ompanies can control what they have to disclose . . . by controlling what they say to the market," and "[s]ilence, absent a duty

[10] Courts sometimes refer to a company "speak[ing] on an issue" as the company putting the issue "in play." See City of Edinburgh, 754 F.3d at 174 ("Wyeth was also not obligated to disclose whether it had changed its criteria for initiating Phase 3, since that fact was likewise not 'in play.'"); Biondolillo v. Roche Holding Ag, No. 17-CV-04056, 2018 WL 4562464, at *5 (D.N.J. Sept. 24, 2018) ("[O]nce the company has put an issue 'in play' by speaking on it, 'it cannot omit material facts related to that issue so as to make its disclosure misleading.'" (quoting Williams, 869 F.3d at 241)).

to disclose, is not misleading under Rule 10b-5." City of Edinburgh, 754 F.3d at 175 (quotation marks omitted).

Here, from the beginning of the Class Period to January 12, 2021, the Company did not speak on the issue of the Bridging Study results. The Company made a series of disclosures explaining that the FDA would be the ultimate decision-maker as to whether the Company's BLA would be accepted; namely (1) on November 2, 2020, the Company noted that its BLA submission would need to be "approved" by the FDA, CAC ¶ 75 (emphasis omitted); Ex. 18 at 1-2; (2) on December 10, 2020, a Company representative stated that it "expect[ed] an advisory committee . . . and . . . would be ready for one if need be," CAC ¶ 91; (3) on January 4, 2021, the Company disclosed that an advisory committee meeting had been scheduled for May 2021, and that the Company "intend[ed] to work closely with the FDA to support their review," CAC ¶ 92 (emphasis omitted); and (4) on January 11, 2021, Palmer stated that the Company "should have an approval decision [from the FDA] on or around July 2 of this year[,] [a]nd especially given the extremely convincing nature of the [Stage 2 clinical trial] data, I think we can all agree that the advisory committee meeting should go well," CAC ¶ 97 (emphasis omitted). None of these disclosures discussed the results of the Bridging Study, nor does the CAC demonstrate that the Company was aware of the results or appreciated a significant risk that the results would negatively impact FDA approval during this time-period. See CAC ¶ 135 ("[T]he Bridging Study results only became available at the beginning of [2021]." (quotation marks omitted)). Thus, the Company did not speak on the issue of the Bridging Study's results and the Company had no duty to disclose the study's results or

an unmaterialized risk associated with them at that time. See SLF Holdings, LLC v. Uniti Fiber Holdings, Inc., 499 F. Supp. 3d 49, 64 (D. Del. 2020) ("[The defendant] had no duty to disclose the alleged, unmaterialized risks."); Hoey v. Insmed Inc., No. 16-CV-4323, 2018 WL 902266, at *9 (D.N.J. Feb. 15, 2018) (explaining that generally, "a study's alleged flaws or shortcomings need not be disclosed to a reasonable investor").

Then, on January 12, 2021, the Company disclosed the results of the Bridging Study—choosing to "speak on [the] issue," Williams, 869 F.3d at 241—and listed the Bridging Study as a "risk factor," CAC ¶ 98; Ex. 21 at 3, explaining that "[t]he results of our PK/PD study . . . may be unacceptable to the regulatory authorities." Ex. 21 at 3. Thus, once the Company chose to speak on the issue of the Bridging Study's results, it disclosed the potential adverse effect of the results on its business. Any omissions concerning the results of the Bridging Study before this point are inactionable.

b

Second, the Company's statements concerning its alternative view of the results of the Bridging Study, announced on January 12, 2021 and repeated thereafter, are not actionable. Several principles guide our analysis.

"Interpretations of clinical trial data are considered opinions" and "[o]pinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." City of Edinburgh, 754 F.3d at 170. There is a "reasonable basis" for a company's interpretation of clinical trial data, for example, when "interim results show[] 'circumstantial evidence of efficacy' for one important patient subgroup." Id. It is also "improbable" that a company did not "honestly believe" its positive interpretation

of initial clinical trial data when the company then contributes "millions of dollars" to further development of the drug after receipt of the clinical trial results. Id.

"Under the PSLRA, alleged misrepresentations are [also] not actionable if they fall within the safe harbor for forward-looking statements," which applies when the statements "are (1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial;[11] or (3) made without actual knowledge that the statement was false or misleading." In re Aetna, Inc. Sec. Litig., 617 F.3d 272, 278 (3d Cir. 2010) (citing 15 U.S.C. § 78u-5(c)). Inactionable forward-looking statements typically include "projections of future performance, plans and objectives for future operations, and assumptions underlying statements about future financial, economic or operational performance." Id. (citing 15. U.S.C. § 78u-5(i)(1)).

Additionally, "statements of subjective analysis . . . or general statements of optimism . . . constitute no more than 'puffery' and are understood by reasonable investors as such," meaning such statements are also inactionable. Id. (citations omitted). For example, a statement that the Company "looks to the future with great optimism" is "clearly inactionable puffing." Shapiro v. UJB Fin. Corp., 964 F.2d 272, 283 n.12 (3d Cir. 1992).

[11] "Although questions of materiality have traditionally been viewed as particularly appropriate for the trier of fact, complaints alleging securities fraud often contain claims of omissions or misstatements that are obviously so unimportant that courts can rule them immaterial as a matter of law at the pleading stage." In re Aetna, 617 F.3d at 283.

Finally, we engage in a "full reading" of a company's statement, rather than a "selective reading" of it, and selective statements of optimism concerning a study are generally not misleading when a company also "explicitly caution[s] investors" that the results of the study are still uncertain. See City of Edinburgh., 754 F.3d at 168-69 (criticizing plaintiffs' "selective reading" of a press release and explaining that "[a] full reading of the [] Release . . . bolsters the [] conclusion that it contained no false statements . . . [as,] [m]ost importantly, the [] Release explicitly cautioned investors that '[n]o conclusion' could be drawn about the Phase 2 interim results until the completion of Phase 2"); id. at 173 (concluding that certain statements were "not actionable" in part because the "speakers were . . . cautious" by "not[ing] [that] the[y] . . . still faced risks establishing [the drug]'s efficacy and safety, and . . . remind[ing] the audience that the final results of the Phase 2 study were not yet available").

Here, the Company's statements concerning its opinion of the results of the Bridging Study are not actionable. The Company had a reasonable basis for its view that "the results of the [] [B]ridging [S]tudy suggest that the drug substances manufactured by AGC Biologics and Eli Lilly are comparable," CAC ¶ 98 (emphasis omitted); Ex. 21 at 3, even though the PK AUC metric did not meet the target range, because (1) the AUC metric was only one metric that a company "may" use to demonstrate PK comparability, CAC ¶ 70; (2) the lower PK AUC metric only "potentially indicate[d] that the [Company's] drug . . . may have cleared faster from the blood stream than the drug substance manufactured by Eli Lilly" and that did not necessarily "impact safety or efficacy" of a drug, Ex. 22 at 5; (3) the PD metric (indicating how the human body reacts

to a drug), and other indicia, appeared to support comparability, Ex. 22 at 5; CAC ¶¶ 112 (Palmer explaining that the "PD parameters" were "within anticipated target" and "are more indicative of the efficacy [and] safety"), 133 (Palmer explaining that "we believe that other relevant PK/PD parameters such as the peak concentration[,] . . . the immunogenicity[,] and the safety profile, all fell within acceptable ranges of comparability"); and (4) the FDA did not reject the Company's interpretation of the Bridging Study results out-of-hand, but instead "indicated that [it] [would] be providing [the Company] with various additional information requests" to better inform its analysis, Ex. 22 at 5. The fact that reasonable people (including the FDA) may have disagreed with the Company's view is inapposite. See, e.g., In re Adolor Corp. Sec. Litig., 616 F. Supp. 2d 551, 567 (E.D. Pa. 2009) ("Plaintiffs' allegations . . . amount to disagreements over the proper methodology and conduct of clinical studies. These allegations are not sufficient to establish falsity for purposes of a Rule 10b–5 claim."); Padnes v. Scios Nova Inc., No. 95-CV-1693, 1996 WL 539711, at *6 (N.D. Cal. Sept. 18, 1996) ("[N]either facts showing reasonable people could have disagreed with defendants' beliefs nor the mere fact that the Phase III tests were unsuccessful, even when coupled with a list of supposed protocol defects, amount to allegations that there was no reasonable basis for the opinions which were expressed.").

Moreover, the CAC does not allege that the Company did not honestly believe its interpretation of the Bridging Study results, and the Company consistently delivered its opinion with a cautionary caveat like "the FDA could disagree with our analysis and interpretation of the [] [B]ridging [S]tudy, including with respect to the observed lower

AUC, and, as a result, could require additional analyses and modeling, or additional information from ongoing or new studies." E.g., Ex. 21 at 3. Thus, the Company's statements concerning its opinion of the Bridging Results are not actionable.

c

Third, statements omitting updates on the Company's interim discussions with the FDA about the Bridging Study after January 12, 2021 until the CRL are not actionable.

"[A] duty to update applies only in 'narrow circumstances' involving more fundamental corporate changes such as mergers, takeovers, or liquidations, as well as when subsequent events produce an 'extreme' or 'radical change' in the continuing validity of the original statement." City of Edinburgh, 754 F.3d at 176 (quoting United States v. Schiff, 602 F.3d 152, 170 (3d Cir. 2010)). "[T]here is no duty to update vague and general statements." Id. Importantly here, companies have "no duty to disclose [] ongoing discussions with the FDA" because "[i]nterim FDA feedback is not material because it does not express a binding agency decision and is subject to change as the FDA and pharmaceutical companies work together to develop viable clinical trials and approvable licensing applications." In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015) (collecting cases), aff'd sub nom. Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016).

Like the court recognized in In re Sanofi, the Company had no duty to disclose interim, non-final discussions with the FDA. Still, the Company did update investors about its discussions with the FDA, stating on February 25, 2021 in its Form 10-K that "[a]t our February 2021 mid-cycle review meeting with FDA, among other matters, we

addressed various questions and preliminary concerns raised by FDA relating to the PK/PD study results and our conclusions," and "[a]t the meeting, FDA indicated that they will be providing us with various additional information requests" but "could not comment on a resolution to its concerns relating to the PK/PD study results." CAC ¶ 101 (emphasis omitted); Ex. 22 at 4. The Form 10-K also warned that "there is no guarantee that the FDA will agree with our analysis and interpretation of the [] [B]ridging [S]tudy," and "as a result . . . the timing of the FDA's review and decision on the teplizumab BLA could be delayed, or its approvability negatively impacted, . . . which would have a material adverse impact on our business." CAC ¶ 101 (emphasis omitted); Ex. 22 at 4.[12] Therefore, the Company did update Plaintiffs on interim FDA discussions and explained the risk to its business posed by those discussions.

Consistent with its obligation, see City of Edinburgh, 754 F.3d at 176, the Company then announced the results of the FDA's CRL four days after the FDA issued it. CAC ¶ 149 (emphasis omitted); Ex. 31 at 3. The Company announced that the CLR concluded that the Bridging Study failed to show PK comparability and the FDA said, "[a]s PK remains the primary endpoint for demonstration of comparability between the two products, [the Company] [would] need to establish PK comparability appropriately between the intended commercial product and the clinical trial product or provide other

[12] Plaintiffs allege that Defendants omitted that they "had not yet conducted a full review of the PK/PD modeling," see CAC ¶ 121(ii), but Plaintiffs fail to identify when Defendants should have disclosed this status update and fail to explain how nondisclosure of this information made a particular statement misleading. Thus, the omission is nonactionable.

data that adequately justify why PK comparability is not necessary." CAC ¶ 149 (emphasis omitted); Ex. 31 at 3. In short, the Company made a timely disclosure once the FDA's decision was final.[13] See City of Brockton Ret. Sys. v. Avon Prod., Inc., No. 11-CV-04665, 2014 WL 4832321, at *24 (S.D.N.Y. Sept. 29, 2014) ("It is also well settled that '[d]efendants are permitted a reasonable amount of time to evaluate potentially negative information and to consider appropriate responses before a duty to disclose arises.'" (quoting In re Elan Corp. Sec. Litig., 543 F. Supp. 2d 187, 217 (S.D.N.Y.2008))); Higginbotham v. Baxter Int'l Inc., 495 F.3d 753, 761 (7th Cir. 2007) ("Taking the time necessary to get things right is both proper and lawful. Managers cannot tell lies but are entitled to investigate for a reasonable time, until they have a full

[13] Because the Company did not know for sure that the BLA was deficient until the FDA's CRL rejected the BLA on July 2, 2021 (particularly given that the Advisory Committee voted in favor of recommending FDA approval of the teplizumab BLA on May 27, 2021, CAC ¶¶ 144-45), and the Company disclosed the FDA's concerns about PK comparability when raised by the FDA and the impact those concerns could have on the BLA approval process, see CAC ¶ 98; Ex. 21 at 3, Plaintiffs' allegations that the Company "overstated the [] BLA's approval prospects," see CAC ¶¶ 76(viii), 79(viii), 82(viii), 86(viii), 90(ix), 93(viii), 99(viii), 104(viii), 108(vii), 110(vii), 113(viii), 115(viii), 119(viii), 121(viii), 140(viii); or made material omissions by not disclosing that the "BLA was deficient in its submitted form," see CAC ¶¶ 76(vi), 79(vi), 82(vi), 86(vi), 90(vi), 93(vi), 99(vi), 104(vi), 108(v), 113(vi), 115(vi), 119(vi), 121(v) & (vi), 140(vi); or "lacked evidentiary support," see CAC ¶¶ 76(vii), 79(vii), 82(vii), 86(vii), 90(viii), 93(vii), 99(vii), 104(vii), 108(vi), 113(vii), 115(vii), 119(vii), 121(v) & (vii), 140(vii); before July 2, 2021 are all nonactionable. See City of Edinburgh, 754 F.3d at 176; see also Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1129 (2d Cir. 1994) ("[M]isguided optimism is not a cause of action [for securities fraud and] . . . [w]e have rejected the legitimacy of alleging fraud by hindsight." (quotation marks omitted)); id. (rejecting allegations of securities fraud when the "the company's disclosures were [not] inconsistent with current data . . . [and instead the allegations] strongly suggest[ed] that the defendants should have been more alert and more skeptical").

story to reveal."). Thus, the Company's omission of additional updates during the interim FDA discussions leading up to the CRL are not actionable.

2

Plaintiffs contend that the Company made misleading statements beginning on November 2, 2020 by omitting that the Stage 2 clinical trial—conducted by NIDDKD and TrialNet—"did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to [] 71 patients." See CAC ¶¶ 76, 79, 82, 83, 86, 90, 93, 99, 104, 108, 113, 115, 119, 121, 123, 140; cf. CAC ¶¶ 60, 144. TrialNet, however, published the enrollment size of its Stage 2 clinical study on August 15, 2019 and specifically stated that the "goal [was] enrolling at least 71 participants" but only "44 [patients were ultimately assigned] to the teplizumab group," undermining Plaintiffs' allegation. See Kevan C. Herold, et al., An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes, 381 New Eng. J. Med. 603-13 (August 15, 2019); CAC ¶ 84; Padnes, 1996 WL 539711, at *7 (holding no material omission when the alleged omission was "fully disclosed" in the "full text of the [] study [that] was published [in a journal]"). Additionally, the Company disclosed in its June 9, 2019 Form 8-K that the Stage 2 clinical trial assigned "44 [patients to] teplizumab." Ex. 5 at 3. Thus, Plaintiffs' allegations fail because both the Company and the entity that conducted the Stage 2 clinical trial publicly disclosed the enrollment size of the Stage 2 clinical trial prior to the beginning of the Class Period.

3

Plaintiffs also contend that the Company made misleading statements beginning on November 2, 2020 by omitting that the Stage 2 clinical trial presented "insufficient" "safety data" and an unclear "overall risk-benefit profile" because, among other things, the trial did not continue to track the "participants who got T[1D] after being treated" with teplizumab. See, e.g., CAC ¶¶ 76, 79, 82, 83, 86, 90, 93, 121. Plaintiffs appear to base these assertions on FDA Advisory Committee members' comments. See, e.g., CAC ¶ 144. Aside from the fact that some of these members nonetheless voted in favor or teplizumab, see Ex. 29, Advisory Committee member concern alone is insufficient to support a securities fraud claim. See In re Medimmune, Inc. Sec. Litig., 873 F. Supp. 953, 966 (D. Md. 1995) ("Nor . . . does it matter that one or more FDA staffers may have questioned MedImmune or its affiliates about the study design during the review process."). Again, "[i]nterpretations of clinical trial data are considered opinions" that are "only actionable under the securities laws if they are not honestly believed and lack a reasonable basis," City of Edinburgh, 754 F.3d at 170, and here Plaintiffs fail to allege that Defendants did not honestly believe that teplizumab was safe over the long term.[14]

[14] Moreover, the Company had a reasonable basis to believe that the safety data from the Stage 2 clinical trial was sufficient without having to continue to track all the patients, evidenced by (1) the "extended follow-up data from the [Stage 2 clinical trial that] . . . showed that a single 14-day course of teplizumab significantly delayed the median onset of T1D in at-risk individuals of approximately three years compared to the placebo," CAC ¶ 102; (2) the fact that "one subject ha[d] yet to develop clinical [T1D] more than eight years after their initial receipt of teplizumab," CAC ¶ 120; (3) the fact that "over 800 patients [] ha[d] been treated with teplizumab through its development lifecycle," CAC ¶ 120; and (4) the fact that the Advisory Committee voted in favor of teplizumab at the very meeting where the Plaintiffs' tracking concerns were first raised, CAC ¶ 145.

Nor did Defendants have a "duty to update" the public on one person's non-dispositive opinion concerning a separate entity's study and follow-ups. See id. at 176. Plaintiff's allegations of material omissions concerning "insufficient" "safety data" and an unclear "overall risk-benefit profile" are therefore not actionable.

4

Plaintiffs contend that that the Company made misleading statements beginning on November 2, 2020 by omitting that its "manufacturing facilities for teplizumab were deficient," CAC ¶¶ 9, 76, 79, 82, 83, 86, 90, 93, 99, 104, 110, 113, 115, 119, 121, 123, 140. Plaintiffs base this allegation on Defendants' July 6, 2021 comment that the FDA noted "certain deficiencies" at the Company's manufacturing facility that would need to be resolved before FDA approval. See CAC ¶ 150. Fatally, the CAC makes no further factual allegations concerning when the Company learned of these deficiencies, the extent or severity of these deficiencies, or whether the deficiencies in fact caused a delay in FDA approval. See In re Medimmune, 873 F. Supp. at 967 (rejecting allegation of securities fraud when "Plaintiffs ha[d] pleaded no specific facts to show why Defendants knew or should have known [something] to be a problem[.]"). Moreover, (1) on March 31, 2020 (before the beginning of the Class Period), the Company disclosed in its Form 10-Q that it was "depend[ent] on third-parties to manufacture [its] product candidates," Ex. 13 at 3, and (2) on November 5, 2020 (days after the beginning of the Class Period), the Company disclosed in its Form 10-Q that "[w]e are completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less

profitable if those third parties fail to obtain manufacturing approval from the FDA," Ex. 19 at 5. Further, the CAC indicates that the Defendants disclosed the FDA's perceived manufacturing deficiency days after the FDA brought it to their attention for the first time in the July 2, 2021 CLR. See CAC ¶ 150. Thus, the Company's alleged omissions concerning manufacturing deficiencies are not actionable.

For these reasons, Plaintiffs fail to allege any actionable misrepresentations omissions, and thus they do not state a claim for relief.

B

Plaintiffs also fail to allege facts from which the Court can infer scienter. "[T]he Supreme Court has defined [scienter] as 'a mental state embracing intent to deceive, manipulate, or defraud.'" Rahman v. Kid Brands, Inc., 736 F.3d 237, 242-43 (3d Cir. 2013) (quoting Tellabs, 551 U.S. at 319). "This scienter standard requires plaintiffs to allege facts giving rise to a strong inference of either reckless or conscious behavior." Institutional Invs. Grp. v. Avaya, Inc., 564 F.3d 242, 267 (3d Cir. 2009) (quotation marks omitted). "[U]nder the PSLRA's '[e]xacting' pleading standard for scienter," a private securities plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Id. at 253 (quoting Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 321 (2007)).

The scienter requirement "obliges courts to weigh the plausible nonculpable explanations for the defendant's conduct against the inferences favoring the plaintiff." Id. at 267 (quotation marks omitted). "A strong inference of scienter is one that is cogent and at least as compelling as any opposing inference of nonfraudulent intent." Id.

(quotation marks omitted). "The pertinent question is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Id. at 267-68 (quotation marks omitted). "Omissions and ambiguities count against inferring scienter." Id. at 268 (quotation marks omitted).

After a "holistic review" of the CAC, the Court concludes that Plaintiffs' allegations do not give rise to a strong inference of scienter as to any Defendant.[15] In re Hertz Glob. Holdings Inc., 905 F.3d 106, 121 (3d Cir. 2018). Concomitantly, the Court concludes the "opposing inference one could draw from the facts alleged," Tellabs, Inc., 551 U.S. at 324, is stronger than the one Plaintiffs seek to draw.

Plaintiffs focus on six allegations to support a strong inference of scienter: (1) teplizumab was centrally important to the Company's business; (2) Palmer and Drechsler held themselves out as knowledgeable about the FDA; (3) Palmer and Drechsler have extensive experience in the pharmaceutical industry; (4) Defendants issued a common stock offering during the class period; (5) Palmer and Drechsler are senior executives at the Company, and (6) Palmer and Drechsler certified the Company's 10-K filings. See CAC ¶¶ 153-66.

[15] The Court of Appeals for the Third Circuit has "neither . . . accepted nor rejected the doctrine of corporate scienter in securities fraud actions." Rahman, 736 F.3d at 246. "[B]ecause the allegations in the [CAC] cannot support the existence of corporate or collective scienter," however, the Court need not examine whether the doctrine should be adopted. Id.

Courts have consistently concluded that allegations like Plaintiffs' are insufficient to support a strong inference of scienter in the absence of other, particularized factual allegations. In Martin v. GNC Holdings, Inc., for example, the Court of Appeals for the Third Circuit explained that "some additional allegation of specific information conveyed to management and related to the fraud" would be required for "the core operation doctrine" to "support a finding of scienter." 757 F. App'x 151, 155 (3d Cir. 2018) (nonprecedential) (quoting Avaya Inc., 564 F.3d at 270); see also, e.g., Lord Abbett Affiliated Fund, Inc. v. Navient Corp., 363 F. Supp. 3d 476, 490 (D. Del. 2019) (same). Similarly, in In re Hertz Global Holdings Inc., the same appellate court explained that "[a]n allegation that a defendant signed a SOX certification attesting to the accuracy of an SEC filing that turned out to be materially false does not add to the scienter puzzle in the absence of any allegation that the defendant knew he was signing a false SEC filing or recklessly disregarded inaccuracies contained in an SEC filing." 905 F.3d at 118; see also, e.g., In re Silvercorp Metals, Inc. Sec. Litig., 26 F. Supp. 3d 266, 277 (S.D.N.Y. 2014) (stating allegations that an individual signed "SEC filings" "would not, standing alone, be sufficient" to show recklessness). The fact certain Defendants held senior level positions also does not give rise to an inference of scienter unless additional, "more specific allegations" are made "linking their positions to their knowledge." Martin v. GNC Holdings, Inc., No. 15-CV-01522, 2017 WL 3974002, at *14 (W.D. Pa. Sept. 8, 2017) (quoting Kennilworth Partners L.P. v. Cendant Corp., 59 F. Supp. 2d 417, 428 (D.N.J. 1999))), aff'd, 757 F. App'x 151 (3d Cir. 2018); see also, e.g., Industriens Pensionsforsikring A/S v. Becton, Dickinson & Co., No. 20-CV-02155, 2021 WL

4191467, at *19 (D.N.J. Sept. 15, 2021) ("Courts routinely reject allegations that a defendant's 'position' within a company, even an important position, creates an inference of scienter."). Likewise, the fact that Defendants were purportedly experts does not, on its own, give rise to a strong inference of scienter.[16] See, e.g., Kates ex rel. MetLife, Inc. v. Kandarian, No. 19-CV-1266, 2020 WL 4287374, at *11 (D. Del. July 27, 2020) ("Allegations of a defendant's experience and expertise . . . are insufficient to raise an inference of scienter." (quoting Abely v. Aeterna Zentaris Inc., No. 12-CV-04711, 2013 WL 2399869, at *18 (S.D.N.Y. May 29, 2013))), R. & R. adopted, 2020 WL 12432745 (D. Del. Sept. 8, 2020); Kasilingam v. Tilray, Inc., No. 20-CV-03459, 2021 WL 4429788, at *9 (S.D.N.Y. Sept. 27, 2021) ("[S]cienter cannot . . . be presumed from a defendant's organizational role or professional expertise."). Finally, a stock offering occurring during a class period is insufficient to give rise to a strong inference of scienter in the absence of additional specific allegations.[17] See, e.g., In re Chembio Diagnostics, Inc., 2022 WL 541891, at *8 ("[I]ndividual employees wanting a specific stock offering

[16] Plaintiffs also do not allege facts from which the Court can infer that Defendants' generally alleged expertise in, for example "preclinical/clinical drug evaluation" or "in the financial and life-sciences industry," CAC ¶¶ 25-26, would have revealed the purported "risks of the Bridging Study to FDA approval," CAC ¶ 158, particularly where the Company's own modeling—which Plaintiffs do not allege to have been deficient—suggested its teplizumab was comparable to Eli Lilly's, cf. In re Synchronoss Techs., Inc. Sec. Litig., No. 17-CV-02978, 2020 WL 2786936, at *15 (D.N.J. May 29, 2020) (concluding that plaintiff had not "demonstrated that scienter can be inferred from the Company's misapplication of [a] complex accounting standard" even though one of the defendants had "experience and training as a CPA").

[17] As discussed herein, the Company's stock offering does not suggest a motive to defraud.

to be successful (but not profiting directly from the sale) is insufficient to infer scienter."); Hoey, 2018 WL 902266, at *22 ("[Defendant]'s secondary offering, in which it raised $331 million for a Phase 3 Trial, also fails to support a strong inference of scienter."); In re Adolor Corp. Sec. Litig., 616 F. Supp. 2d 551, 573 (E.D. Pa. 2009) ("[T]hat Defendants stood to benefit from [defendant]'s public stock offering . . . [is] not the type of financial benefits that support a finding of scienter."); Cozzarelli v. Inspire Pharms. Inc., 549 F.3d 618, 627 (4th Cir. 2008) ("[A] strong inference of fraud does not arise merely from seeking capital to support a risky venture. . . . All investments carry risk, particularly in a field like biopharmaceuticals.").

Here, such additional allegations are absent. Although Plaintiffs allege that Palmer and Drechsler "knew facts or had access to information suggesting that their public statements were not accurate or failed to check the information they had a duty to monitor," CAC ¶ 165, and assert, in light of the importance of teplizumab to the Company, that it is "inconceivable" Defendants would not know about the purported issues with the Bridging Study and Stage 2 clinical trial, CAC ¶ 155, Plaintiffs nowhere describe the allegedly contradictory information or otherwise provide factual allegations bolstering their conclusory assertions, see Pl. Br. at 36-38.[18] Instead, Plaintiffs appear to

[18] To take one example, the CAC contains several statements in which Defendants stated their belief that the "results of the [Bridging] [S]tudy suggest[ed] that the drug substances manufactured by AGC Biologics and Eli Lilly are comparable" notwithstanding "a lower AUC." CAC ¶ 101. Plaintiffs, however, do not allege that Defendants' belief was unfounded or that Defendants possessed any information suggesting their beliefs or analyses were incorrect prior to the FDA's final feedback. Cf. In re Chembio Diagnostics, Inc. Sec. Litig., No. 20-CV-02706, 2022 WL 541891, at *10

argue that they have plausibly alleged scienter as to most of the at-issue statements simply because some or all Defendants had access to, or were aware of, the contents of the Bridging and Stage 2 studies. Given the nature of Plaintiffs' allegations, and for the reasons discussed above, however, such allegations are insufficient.[19]

Plaintiffs also appear to argue that because the FDA conveyed in July 2021 that it found "certain deficiencies" at a fill/finish facility used by the Company, that many of Defendants at-issue statements were made with scienter. The CAC, however, contains no allegations speaking to when the deficiencies arose or whether anyone at the Company knew or was reckless in not knowing about them. Cf. Witriol v. Conexant Sys., Inc., No. 04-CV-06219, 2006 WL 3511155, at *4 (D.N.J. Dec. 4, 2006) ("To plead scienter, it is

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(E.D.N.Y. Feb. 23, 2022) ("As applied to this case, the officer and director defendants' actions would have been reckless if defendants knew, but did not disclose, that it was inevitable that [Defendant] would lose its EUA."), reconsideration denied, 2022 WL 2872671 (E.D.N.Y. July 21, 2022). Further, the fact that the FDA ultimately disagreed does not, alone, support the inference that Defendants acted with scienter when making the at-issue statements. See, e.g., OFI Asset Mgmt. v. Cooper Tire & Rubber, 834 F.3d 481, 497 (3d Cir. 2016) (noting the Court of Appeals for the Third Circuit has long rejected attempts to "prove fraud by hindsight"); cf. In re Sanofi-Aventis Sec. Litig., No. 07-CV-10279, 2009 WL 3094957, at *7 (S.D.N.Y. Sept. 25, 2009) ("Even the subsequent denial of FDA approval based on a review of the same available evidence does not support a conclusion of recklessness.").

[19] Given that the Stage 2 clinical trial's enrollment numbers had been disclosed before the class period began, Defendants' purported failure to disclose the enrollment size does not support an inference of scienter. Rather, "[t]he most plausible inference, instead, is benign: that [D]efendants believed that they had reported [the enrollment] and felt no need to repeat that . . . disclosure in every later statement." In re Sanofi Sec. Litig., 87 F. Supp. 3d at 547-48.

In addition, as discussed above, Defendants had no duty to disclose much of what Plaintiffs contend Defendants omitted. This also cuts against a strong inference of scienter. See Kalnit v. Eichler, 264 F.3d 131, 144 (2d Cir. 2001) ("Because . . . this case does not present facts indicating a clear duty to disclose, plaintiff's scienter allegations do not provide strong evidence of conscious misbehavior or recklessness.")).

not sufficient to allege that [an aspect of the business] was problematic or that [unlawful activity] occurred. The key issue is what the individual Defendants knew about the [business] problems and the [unlawful activity], or whether these were so obvious that the Defendants must have been aware of them."); Rice as Tr. of Richard E. & Melinda Rice Revocable Fam. Tr. 5/9/90 v. Intercept Pharms., Inc., No. 21-CV-0036, 2022 WL 837114, at *22 (S.D.N.Y. Mar. 21, 2022) (no "strong inference of scienter in [defendants'] failure to convey . . . information" where the "complaint does not allege with particularity that [d]efendants knew . . . of the [documents containing contrary information]" at the time of certain purported misrepresentations). This is true even as to the Defendants' specific statements about manufacturing, see CAC ¶¶ 80, 89, 122, 150; Plaintiffs do not allege facts linking the deficiencies identified in July 2021 to those prior statements—e.g., were they at the same facility, were the issues contemporaneous, and so forth.

Last, Plaintiffs also contend that the fact that Defendants spoke about the Bridging Study supports scienter. See Pl. Br. at 35 & n.11. "[T]he content and context of [the] statements themselves" can provide "powerful evidence of scienter." Avaya, Inc., 564 F.3d at 269. Here, however, the content and context cut the other way. In each instance Plaintiffs cite, Defendants also discussed purported issues with the Bridging Study that Defendants allege Plaintiffs concealed. See CAC ¶ 112 ("[A]ll of the parameters were within anticipated target[s] . . . with the exception of this AUC PK area under the curve. And that the AGC Biologics [sic] sales were slightly below the target, indicating that it cleared a little faster."); ¶ 114 ("However, there was one [PK] component, which we refer

to as the area under the curve, . . . and that component in that particular study missed the target by an amount not terrifically sort of [sic] larger significant amount, but it fell below that target. . . . [The FDA] told us that they want to do their own modeling . . . [and] may well have information requests for us in terms of interrogating that modeling and our conclusions."); ¶ 122 ("There was one PK parameter, area under the curve, which is really suggesting the rate at which the material clears from the blood stream . . . and it suggested the AGC product might clear a little faster."); ¶ 124 ("We don't anticipate that this would be an [Advisory Committee] issue . . . . [W]e are hopeful that when the agency has had a chance to do its modeling and address all of its information request that they have come to the same conclusion that we have."); see also Ex. 28 at 19 ("The Agency is actively working with the Applicant to try to resolve this issue in a timely manner, and input on the bridging data is not being sought from the committee."); CAC ¶ 131. Thus, Defendants expressly acknowledged that the Bridging Study showed a lower AUC, explained their basis for concluding their teplizumab was comparable to Eli Lilly's, and relayed the FDA's actions and responses. These factors both undercut an inference of scienter and distinguish this case from the ones Plaintiffs cite. See, e.g., Roofer's Pension Fund v. Papa, No. 16-CV-02805, 2018 WL 3601229, at *21-22 (D.N.J. July 27, 2018) (allegations "narrowly surpassed the bar for pleading scienter" where, for example, defendants "were high-ranking executives allegedly involved in the pricing decisions at issue," spoke about personal involvement in pricing decisions, plaintiffs alleged a price fixing scheme through which the corporate entity defendant "reaped hundreds of millions of dollars," and "the Department of Justice raided [the corporate

defendant's] offices as part of a criminal price-fixing probe"); Frater v. Hemispherx Biopharma, Inc., 996 F. Supp. 2d 335, 349 (E.D. Pa. 2014) (allegations gave rise to strong inference of scienter where, among other things, Defendants withheld important information already conveyed by the FDA and made statements that were allegedly "outright false" in light of the FDA's activity).

In addition, although motive and opportunity are not the sine qua non of scienter, they are still relevant to a court's holistic analysis. See Hoey, 2018 WL 902266, at *21-22. Plaintiffs contend that Defendants were motivated to commit fraud because they needed capital, and they would be unable to raise it if the "true risks to teplizumab's FDA approval were disclosed to investors." Pl. Br. at 41. Plaintiffs' allegations, however, do not provide a plausible motive.

As an initial matter, courts have concluded that similar theories are inadequate because, among other things, the desire to raise funds is motive shared by all corporate executives and officers, and "a motivation of avoiding an event that would threaten the survival of a company is . . . too generalized (and generalizable)." In re Chembio Diagnostics, Inc., 2022 WL 541891, at *9 (quotation marks omitted) (collecting cases); see also, e.g., Hoey, 2018 WL 902266, at *21-22; Gillis v. QRX Pharma Ltd., 197 F. Supp. 3d 557, 600-01 (S.D.N.Y. 2016); MHC Mut. Conversion Fund, L.P. v. Sandler O'Neill & Partners, L.P., 761 F.3d 1109, 1122 (10th Cir. 2014).[20]

[20] Tomaszewski v. Trevena, Inc., the only case Plaintiffs cite, is not binding and distinguishable in any event. 482 F. Supp. 3d 317 (E.D. Pa. 2020). There, the court concluded that scienter was adequately alleged where, in addition to "need[ing] to raise

Moreover, Plaintiffs' motive argument is undermined by the fact that the public offering document forming the basis of Plaintiffs' assertion reveals what is, in effect, a crucial fact that Plaintiffs allege Defendants were concealing—i.e., that the Bridging Study "show[ed] a lower area under the curve" and that "[t]he FDA could disagree with [the Company's] analysis and interpretation of . . . the [B]ridging [S]tudy, including with respect to the observed lower AUC . . . ." CAC ¶ 98.[21] If Defendants intended to hide purported risks to FDA approval so as to raise additional funds, they would presumably not have disclosed in the document underlying the fundraising the purported shortcoming giving rise to the risk before to the FDA provided any feedback on the issue.

Ultimately, the "opposing inference one could draw from the facts alleged" is stronger than the inference Plaintiffs ask this Court to draw. Tellabs, Inc., 551 U.S. at 324. That is, Defendants thought and hoped they would obtain FDA approval, disclosed obstacles to approval when they arose and that approval was uncertain, and reported that

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funds," one of the Defendants also "made statements expressing that the FDA approved of the Phase 3 program without disclosing the FDA's serious disagreements" of which he knew. Id. at 333-35. Here, Plaintiffs do not allege that the FDA provided any feedback concerning the approval prospects of teplizumab at the time of the offering, including with respect to the Bridging Study, potential issues with which Defendants nonetheless disclosed.

[21] Other information the Company is alleged to have concealed that purportedly heightened the risk of non-approval was either already disclosed (e.g., the enrollment level of the Stage 2 clinical trial), not plausibly alleged to have yet come to pass (e.g., manufacturing issues), or not alleged to have yet been highlighted by the FDA (or anyone else) as a factor increasing the risk of non-approval (e.g., the various purported other issues with the Stage 2 clinical trial). See CAC ¶¶ 8-9 (noting four overarching purported misrepresentations or omissions). Plaintiffs also do not allege other indicia of motive like unusual stock trading that, although not dispositive, nevertheless informs the Court's holistic analysis.

they were ultimately wrong about both the timeline and that their Bridging Study data would be found satisfactory.

Plaintiffs have, therefore, failed to allege scienter as to any Defendant.

C

Plaintiffs also fail to allege loss causation. Loss causation is "a causal connection between the material misrepresentation and the loss." Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 342 (2005). Simply put, loss causation "requires the plaintiff [ultimately] to prove that it was the very facts about which the defendant lied which caused its injuries." Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 222 (3d Cir. 2006) (quotation marks omitted); see also, e.g., McCabe v. Ernst & Young, LLP, 494 F.3d 418, 425-26 (3d Cir. 2007) ("[T]o satisfy the loss causation requirement, the plaintiff must show that the revelation of that misrepresentation or omission was a substantial factor in causing a decline in the security's price, thus creating an actual economic loss for the plaintiff."). Accordingly, at this stage, "[p]laintiffs must . . . . adequately allege that, when the truth was revealed about th[e] fraudulent statements, [p]laintiffs suffered an economic harm as a result." City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp, 908 F.3d 872, 883 (3d Cir. 2018); see also Dura Pharms., 544 U.S. at 346 ("Our holding about plaintiffs' need to prove proximate causation . . . leads us also to conclude that the plaintiffs' complaint here failed adequately to allege th[is] requirement[].").

Plaintiffs claim to be asserting "a combined corrective disclosure/materialization of the risk theory." Pl. Br. at 49. Under a corrective disclosure theory, a plaintiff posits that the false nature of the information is revealed by a later partial or full disclosure of

truthful information and, following such disclosure, the stock price drops. See, e.g., De Vito v. Liquid Holdings Grp., Inc., No. 15-CV-06969, 2018 WL 6891832, at *39 (D.N.J. Dec. 31, 2018). "Under the materialization of the risk theory, [p]aintiffs can prove loss causation by showing, [for example,] an event that reveals that an earlier statement was false, or in other words, by showing the materialization of a risk that was misrepresented by the Company." Howard v. Arconic Inc., No. 17-CV-01057, 2021 WL 2561895, at *17 (W.D. Pa. June 23, 2021).[22] That said, the two are "not wholly distinct theories of loss causation." In re Vivendi, S.A. Sec. Litig., 838 F.3d 223, 262 (2d Cir. 2016).

Because Plaintiffs' allegations do not show Defendants made materially false or misleading statements or omissions, Plaintiffs have failed to allege Defendants caused Plaintiffs' loss.[23] See, e.g., In re Amarin Corp. PLC Sec. Litig., No. 19-CV-06601, 2021

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[22] Although the Court of Appeals for the "Third Circuit has not adopted the materialization of the risk theory . . . , district courts in this Circuit have applied it . . . , [a]nd the Third Circuit has discussed the theory without rejecting it." Howard, 2021 WL 2561895, at *17 n.14 (citations omitted); cf. Bartesch v. Cook, 941 F. Supp. 2d 501, 512 (D. Del. 2013) ("The Third Circuit has not adopted the 'materialization of risk' test but, instead, requires that there have been corrective disclosures that exposed the alleged fraud.").

[23] Given this conclusion, the Court need not address whether Plaintiffs must meet Rule 9(b) in pleading loss causation. Hall v. Johnson & Johnson, No. 18-CV-01833, 2019 WL 7207491, at *27 (D.N.J. Dec. 27, 2019) (noting that "the Third Circuit has not yet addressed" the proper pleading standard, but that the courts "of this district have consistently analyzed loss causation under Rule 8(a), rather than the more stringent requirements of Rule 9(b)"); accord McDermid v. Inovio Pharms., Inc., 520 F. Supp. 3d 652, 665 (E.D. Pa. 2021); see also Dura Pharm., Inc., 544 U.S. at 346.

Additionally, to the extent Defendants argue that disclosures cannot be partial, they are incorrect. See, e.g., Allegheny Cnty. Employees' Ret. Sys. v. Energy Transfer LP, 532 F. Supp. 3d 189, 239 (E.D. Pa. 2021) ("[T]he truth may be revealed by a series of partial disclosures through which the truth gradually leaks out."); De Vito, 2018 WL

WL 1171669, at *16 (D.N.J. Mar. 29, 2021) ("Because Plaintiffs do not properly plead Defendants made an actionable misstatement or omission, the Court need not address whether Plaintiffs adequately pled loss causation."), aff'd, No. 21-2071, 2022 WL 2128560 (3d Cir. June 14, 2022); Takata v. Riot Blockchain, Inc., No. 18-CV-02293, 2020 WL 2079375, at *13 (D.N.J. Apr. 30, 2020) (noting it would be "difficult" to assess Defendants' loss causation arguments after the court concluded that "[p]laintiff . . . failed to adequately allege that any of the statements identified . . . were materially false or misleading"); In re Zillow Grp., Inc. Sec. Litig., No. 17-CV-01387-JCC, 2018 WL 4735711, at *17 (W.D. Wash. Oct. 2, 2018) ("Plaintiffs have failed to allege loss causation because the amended complaint does not adequately plead any material misleading statements by Defendants.").[24]

III

For the foregoing reasons, Defendants' motion will be granted.

6891832, at *39 (same); see also In re DVI, Inc. Sec. Litig., No. 2:03-CV-05336, 2010 WL 3522090, at *6 (E.D. Pa. Sept. 3, 2010) ("[A] 'corrective disclosure' must reveal at least part of the falsity of the alleged misrepresentation, and it must reveal new information to the market.").

[24] Because Plaintiffs have failed to allege a predicate violation of Section 10(b), their claims arising under Section 20(a) must also be dismissed. In re Merck & Co., Sec. Litig., 432 F.3d 261, 275-76 (3d Cir. 2005).